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EXAMINER	
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ART UNIT	PAPER NUMBER
1213	4

DATE MAILED: 1213

02/15/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

see attachment

Office Action Summary

Application No.

08/429,494

Applicant(s)

Anders Williamsson et al.

Examiner

Harold Pyon

Group Art Unit

1313



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

Drawings

1. The drawings are objected to under 37 C.F.R. § 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the aspect of "two substantially planar surfaces are parallel and the distance therebetween is less than the distance between the inner surfaces defining the measuring zone" and "the distance between the two substantially planar surfaces of the body member increases in a direction extending away from the inner end wall of the inner peripheral zone" must be shown or the feature cancelled from the claim. No new matter should be entered.

Claim Rejections - 35 USC § 112

2. Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, "substantially parallel" lacks definitiveness because "substantially parallel" imply something less than parallel; lines 5 and 6, "a channel of higher capillary force than the measuring zone" is vague and indefinite. It is unclear how to achieve the higher capillary force in the inner peripheral channel compare to the measuring zone. It is also unclear how the structure of the sample inlet and an inner channel are connected to the measuring zone. In other word, how

the sample is getting into the measuring zone from the inlet. There is no connecting structure between the measuring zone and the inlet or the outlet; line 6, the term "higher" is a relative term. How higher is high? The claims should positively set forth the purpose of the apparatus and the structure necessary for carrying out that purpose, i.e. the claim is incomplete for getting the sample from the inlet to the measuring zone, structurally.

In claims 2-4, the term "substantially planar surface" lacks definitiveness because the term imply something less than planar surface.

In claim 3, the phrase "the two substantially planar surfaces are parallel and the distance therebetween is less than the distance between the inner surfaces defining the measuring zone" is vague and unclear. It is unclear what the applicants are claiming that the distance between the inner wall of the measuring zone has smaller distance than two planar surfaces of the body member (cavity?). What is the two substantially planar surface?

In claim 4, it is unclear how the two substantially planar surface of the body member increases in a direction extending away from the inner end wall of the inner peripheral zone. The drawing does not show the claimed aspect of "increases in direction".

In claim 8, what is the azidmethemoglobin method? The specification refer to Vanaetti of J. Lab. Clin. Med. 67, 116-26 (1966), but the specification does not explain how to carry out the azidmethemoglobin method in page 5. Clarification or/and correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2,5,7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fielding.

Fielding teaches an integral capillary microcuvette for use in determining the hemoglobin content of whole blood(column 1, lines 19-20) comprising a body member(Fig.1) and a cavity including a measuring zone(Fig.2, #17, Fig.4, #24) within the body member, the cavity being defined by two opposite(Fig.1, #10,#16), substantially parallel inner surface of the body member(Fig.1), an outer peripheral edge including a sample inlet(Fig.2, #13) and an inner peripheral zone having a channel of higher capillary force than the measuring zone(Column 2, lines 49-52), both ends of the channel communicating with the exterior of the microcuvette(Fig.1, #II); wherein the channel is defined by an inner end wall of the inner peripheral zone and two

substantially planar surfaces of the body member (Fig. 1, column 2, lines 43-44); wherein the cavity has predetermined volume (Fig. 2); and wherein the measuring zone has depth that does not exceed 0.15 mm (column 2, lines 27-28).

Claim Rejections - 35 USC § 103

5. Claims 3-4, 6, 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Fielding in view of Chang et al.

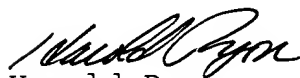
Fielding teaches an integral capillary microcuvette as described above (see Fielding supra). Fielding fails to disclose the cavity includes a dry reagent in a predetermined amount, and that hemoglobin is determined by the azidmethemoglobin method. However, Fielding suggest that it is a well known in the art to determine hemoglobin content by chemical treatment to carry out the hemoglobin test (column 1, lines 27-32). Moreover, Chang et al. teach that mixing the sample with a reagent and directly making optical analysis of the sample mixed with the reagent is well known in the art. Thus, one of ordinary skill in the art would have been recognized to incorporate mixing of the predetermined amount of the chemical with such as the dry reagent as taught by Chang et al. into the primary reference to accurately determine the hemoglobin content of a patient's blood. As to claim 8, applicants are introducing method limitation into apparatus claims and, hence, such are given little patentable weight. As to claims 3-4, claims may have a patentable subject matter over the prior art. However, it is unclear that what the

structure is being claimed. Thus, examiner assumes that Fielding disclose the claimed aspect of the two parallel planar surface is less than the distance between the inner surface of the measuring zone (Fig.1-3) and the aspect of the surface of the body member increases in a direction extending away from the inner end wall of the inner peripheral zone(Fig.6).

It would have been obvious to one of ordinary skill in the art at the time applicants' invention was made to have modified Fielding with a well known dry chemical as taught by Chang et al. in order to accurately determine the content of hemoglobin.

6. Rossiter, Columbus, Muller(5,030,421 and 5,260,032), Polanyi, Kuntz et al(4,865,812 and 4,981,654), Gross, Blatt et al., and Clark et al. are cited of interest to show the state of the art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harold Pyon whose telephone number is (703) 308-4251.


Harold Pyon
February 3, 1996